IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG,	)	
Plaintiffs,	)	C.A. No. 12-1032-GMS
v.	)	
WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC,	)	
Defendants.	)	

PLAINTIFFS' CLAIM CONSTRUCTION ANSWERING BRIEF

OF COUNSEL:
Adam K. Mortara
Matthew R. Ford
Andrew C. MacNally
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 W. Hubbard Street, Suite 300
Chicago, IL 60654
(312) 494-4400

Sundeep K. (Rob) Addy
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
1899 Wynkoop Street, 8th Floor
Denver, CO 80202
(303) 592-3100

Richard D. Kirk (#922)
Stephen B. Brauerman (#4952)
Vanessa R. Tiradentes (#5398)
Sara E. Bussiere (#5725)
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899
(302) 655-5000

Attorneys for Plaintiffs Bayer Intellectual Property GmbH and Bayer Pharma AG

June 13, 2014

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

ARGUMENT

I. The Whereby Clause Does Not Claim A Science-Defying Super-Regimen

Warner Chilcott's proposed constructions of the terms in the whereby clause require the Court to engage in a two-step analysis.[1] First, Warner Chilcott asks the Court to find that Bayer disavowed claim scope, stating that no prior-art regimen had any of the characteristics set out in the whereby clause. Second, Warner Chilcott asks the Court to construe each element as an improvement over every prior-art regimen in the patent's specification. Both steps invite error.

A. Bayer Patented A Novel Regimen That Produces The Combination Of Characteristics Recited In The Whereby Clause

1. Bayer Did Not Disavow Claim Scope

Absent from Warner Chilcott's claim-construction brief is any acknowledgement of the high burden that it must meet to establish that its constructions are proper. Warner Chilcott's proposed constructions of the whereby clause amount to claim disavowal – that is the inventors' disavowing that the results achieved by prior-art regimens would fall within the otherwise plain meaning of the whereby clause. "The standard for disavowal of claim scope is . . . exacting." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). Warner Chilcott points to two potential sources of claim disavowal: the specification, and the prosecution history. [D.I. 62, WC Br. at 5-6.] Neither source provides any evidence of disavowal, let alone a "clear and unmistakable disclaimer."

First, the patent itself does discuss the "advantages" of the claimed regimen over "previously described preparations, especially those with a daily ethinylestradiol dose of less than 30 μg and those with a prolonged pill-free interval." [Ex. 1, U.S. Pat. No. 5,980,940 at 6:9-15 ("'940 Pat.").] But "[m]ere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal." *Thorner*, 669 F.3d at 1366; *Epistar Corp. v. Int'l*

[1] Bayer does not dispute Warner Chilcott's definition of the person of ordinary skill in the art for purposes of claim construction.

Trade Comm'n, 566 F.3d 1321, 1335 (Fed. Cir. 2009) ("A patentee's discussion of the shortcomings of certain techniques is not a disavowal of the use of those techniques in a manner consistent with the claimed invention."). And the criticisms in the patent do not constitute "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope" because the specification does not exclude the prior-art regimens from the whereby clause. *Epistar Corp.*, 566 F.3d at 1334.

Second, the prosecution history does not show claim disavowal. Warner Chilcott divides the characteristics listed in the whereby clause when discussing the prosecution history and argues that Bayer claimed to have achieved each of these results "for the first time." For example, when discussing its proposed construction of "high contraceptive reliability," Warner Chilcott argues that Bayer said during prosecution that its novel regimen "provided this [high] reliability '*for the first time*.'" [D.I. 62, WC Br. at 9 (emphasis in original).] Likewise, Warner Chilcott argues that Bayer said during prosecution that its regimen achieved "satisfactory cycle control" and "reliable avoidance of intracyclic menstrual bleeding," each "for the first time." [D.I. 62, WC Br. at 14-15.]

These arguments distort the prosecution history. The Examiner first rejected Bayer's application in light of the Pasquale and Ehrlich references. Bayer added the whereby clause and distinguished its amended claims on three grounds. First, Pasquale's regimen could result in follicular development very early on in the cycle, as discussed in the '940 patent's specification. Second, the '940 patent claimed a regimen with both low estrogen and low total hormonal amounts, unlike the prior art. [Ex. 9, U.S. Pat. No. 5,980,940 Prosecution History at 91.] Finally, the '940 patented regimen produced a ***combination*** of characteristics that was not in the prior art. [*Id.*] The language is clear that Bayer was claiming the combination of characteristics "for the first time":

> There is no teaching in the cited prior art that an estrogen could be administered in low effective amounts by the claimed regimen, wherein each individual dosage unit has a very low effective estrogen content and a very low effective total hormone content per administration cycle, and whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of

> intracyclic menstrual bleeding and undesirable side-effects. ***The present invention provided such a low-dose, contraceptively effective pharmaceutical combination preparation for the first time.***

[*Id.* (emphasis added).] The prosecution history does not support Warner Chilcott's claim that Bayer was saying it had achieved any particular effect "for the first time" or that it disavowed the results achieved in the prior art as insufficient under the whereby clause. Instead, for the reasons set forth in Bayer's opening brief, the plain meaning of the claim should govern. [D.I. 61, Bayer Br. at 8.] That plain meaning does not call for the comparison that Warner Chilcott seeks to impose through a flawed disavowal theory.

2. Warner Chilcott's Proposed Constructions Would Result In A Regimen That Is Scientifically Impossible

The Court should not assume that Bayer patented a regimen that is scientifically impossible. That would be error. *AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1276 (Fed. Cir. 2011) (rejecting construction that would violate science governing crystals by "at once requir[ing] two distinct crystalline structures and a single, uniform crystalline structure"). But that is what Warner Chilcott proposes. The characteristics set out in the whereby clause are interrelated, and an oral-contraceptive regimen cannot outperform every prior-art regimen in every category.

For example, the patent recognizes that (all else being equal) lower estrogen content is associated with worse cycle control. [Ex. 1, '940 Pat. at 2:59-61 ("The cycle control of [prior art] preparation [with lower estrogen] is somewhat less good than that of preparations with a higher estrogen dose.").] Thus, an oral contraceptive with higher estrogen amounts will generally result in better cycle control than low-dose estrogen regimens. [Ex. 17, R. Hatcher, et al., *Contraceptive Technology* 259 (16th ed. 1994) ("both spotting and breakthrough bleeding are more common among users of low-dose OCs than among users of high-dose pills").]

But the intrinsic evidence also recognizes that higher doses of estrogen result in a worse side-effect profile. In fact, a desire to reduce the associated side effects caused by high doses of

estrogen has driven much of the development of new oral-contraceptive regimens. [Ex. 11, U.S. Pat. No. 5,583,129 at 1:57-59 ("The reduction of the daily hormone dose was connected with the expectation to minimize the frequency of undesired side effects.").] A person of skill in the art recognized that lower estrogen results in a better side effect profile. [Ex. 17, R. Hatcher, et al., *Contraceptive Technology* 241 (16th ed. 1994) ("[I]f one's therapeutic goal is to minimize the risk of a specific side effect that is usually related to the estrogenic component of pills, such as nausea or breast tenderness, the clinician may again choose the pill with lowest amount of ethinyl estradiol.").]

Under Warner Chilcott's proposed construction, however, Bayer invented a regimen that can defy the laws of contraceptive science. That is, Bayer's regimen has "an estrogen content that is as low as possible" but with better cycle control and less intracyclic menstrual bleeding than regimens with much more estrogen, such as those set out in the prior art. [Ex. 6, U.S. Pat. No. 4,921,843 at 6:20-7:45 ("Pasquale"); Ex. 7, U.S. Pat. No. 3,502,772 at 3:11-4:46 ("Ijzerman").] That is impossible, and Courts "strive, where possible, to avoid nonsensical results in construing claim language." *AIA Eng'g Ltd*, 657 F.3d at 1276. [*See also* D.I. 61, Bayer Br. at 8-10; *see also Declaration of Lee P. Shulman, MD, filed contemporaneously (hereafter "*Shulman Decl.") ¶ 27[2].]

B. Each Term Has A Known Meaning In The Art

1. Plain Meaning Does Not Mean "Singular, Commonly Understood Meaning"

[2] Bayer has provided an expert declaration in opposition to the declaration of James A. Simon, MD offered by Warner Chilcott (D.I. 63). Bayer does not believe that the Court generally values expert testimony during claim construction or that these declarations are necessary for claim construction or envisioned by the scheduling order entered in this case. But Bayer has submitted the Shulman Declaration so that Warner Chilcott's declaration does not stand unopposed.

Warner Chilcott argues without citing a single case in support that a term must have a "singular, commonly understood meaning" in order to have a plain and ordinary meaning.[3] Warner Chilcott's expert repeats this phrase as though it governs the Court's inquiry.

But that is not the standard for claim construction. "[A] sound claim construction need not always purge every shred of ambiguity. The resolution of some line-drawing problems – especially easy ones like this one – is properly left to the trier of fact." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact."). That is also true when patents or constructions contain comparative or functional language. *Funai Elec. Co. v. Daewoo Elecs. Corp.*, 616 F.3d 1357, 1366 (Fed. Cir. 2010) ("The use of comparative and functional language to construe and explain a claim term is not improper. . . . There was evidence in the district court that persons experienced in this field would understand this description of the insulating material, in the context in which it is used . . . .").

2. When Developing Oral Contraceptives, A Person Of Ordinary Skill Compares The Effects Of An Oral Contraceptive To A Normal Menstrual Cycle Of A Healthy Woman

At the time of the patent, persons of ordinary skill in the art evaluated the effects of an oral contraceptive by comparing the effects of the contraceptive to healthy women who are not taking oral contraception. In many studies, there was a control cycle for the women treated in the study followed by treatment cycles that assessed the effect of the oral contraceptive on the menstrual cycle and its other effects. [Ex. 18, R. Wenzl, et al., *Ovulation inhibition with combined oral contraceptive containing 1 mg micronized 17β estradiol*, 60 Fertility & Sterility 616, 617-18 (1993) ("The complete study

[3] This is also not the standard for definiteness. *See Nautilus Inc. v. Biosig Instruments*, 134 S. Ct. 2120, __ U.S. __ (2014).

consisted of a screening cycle, followed by two treatment cycles and an after treatment cycle.") (comparing treatment to "screening cycle"); Ex. 19, D. Serfaty, *The 20 microgram ethinyl estradiol plus 150 microgram desogestrel pill multicenter study on 235 women for 6 months*, 18 Contraception 1, 6 (1990) (WC_DEL_00036391-99); *see also* Ex. 20, L. Kovacs & H. Hoffmann, *A new low-dose oral contraceptive containing ethinylestradiol, estradiol and dienogest: first experience of its clinical use*, in Extragenital Effects of Oral Contraceptives 39-41 (June 1996) (comparing "follicle size and serum levels" of hormones "compared with the control cycle"); *see also* Shulman Decl. ¶¶ 12-13.]

This has not changed and is how Warner Chilcott evaluated Lo Loestrin FE. The director for the clinical study for Lo Loestrin explained why a "control cycle" is "standard" for assessing the effect of a contraceptive:

> Q. And then the next bullet point has got certain parameters on the follicle-stimulating hormone levels and progesterone. What was the reason behind that as an inclusion criteria?
>
> A. We wanted to know that these were women who were ovulating at baseline. This is standard in this sort of a trial to do the study for three or four or five cycles. ***The first cycle is always an off-treatment cycle to show that ovulation is occurring. So if you are looking for suppression of ovulation in your treatment cycles, you know that in fact it is an ovulatory woman you are studying.***

[Ex. 21, Ellman Dep. 66:9-24, Feb. 8, 2013 (emphasis added) (WC_DEL_00076511).]

3. The Court Should Reject Warner Chilcott's Proposed Constructions

a. High Contraceptive Reliability

The parties' proposed constructions of "high contraceptive reliability" differ in two respects. First, Warner Chilcott proposes a construction that uses "contraceptive efficacy," and Bayer proposes a construction that uses the claim language "contraceptive reliability." The difference between "efficacy" and "reliability" is not material to the disputed claim constructions. As demonstrated below, sources use the terms contraceptive reliability and efficacy or effectiveness interchangeably to describe the ability of an oral contraceptive to prevent pregnancy. [*E.g.*, Ex. 6, Pasquale at 1:10-13.]

Instead, the core of the parties' dispute concerns the meaning of the word "high." Warner Chilcott claims that "high contraceptive reliability" did not have a known meaning in the art. To the contrary, it did and does. An oral contraceptive has high contraceptive reliability when there is a low-rate of pregnancy when using the contraceptive when compared to healthy women who are not using hormonal contraception. [Ex. 1, '940 Pat. at 3:36-39 (discussing "risk of pregnancy" when "[c]ontraceptive protection is thus jeopardized").] A person of ordinary skill in the art assesses whether an oral contraceptive has "high contraceptive reliability" by testing the oral contraceptive on healthy women and assessing the risk of pregnancy while the women were taking the oral contraceptive. [*See, e.g.*, Ex. 22, P. Darney, *Safety and efficacy of a triphasic oral contraceptive containing desogestrel*, 48 Contraception 323, 324 (1993); *see also* Shulman Decl. ¶ 13.]

In the context of oral contraceptives, a person of ordinary skill in the art has no difficulty determining when the contraceptive reliability of an oral contraceptive is "high." The intrinsic evidence frequently characterizes contraceptive reliability or efficacy as "high," which is proof of a plain and ordinary meaning. *Laryngeal Mask Co. v. Ambu*, 618 F.3d 1367, 1373 (Fed. Cir. 2010) ("Although there was no dictionary or treatise definition introduced for backplate, there are two prior art patents also related to laryngeal mask devices which use the term."). The Ehrlich patent states that its regimen provides "high contraceptive reliability." [Ex. 2, U.S. Pat. No. 5,280,023 at 3:37-38 ("Ehrlich").] The Lachnit patent states that its claimed regimen has "high contraceptive reliability." [Ex. 15, U.S. Pat. No. 5,756,490 at 3:43-52 ("Lachnit").] The Pasquale patent states that "new lower-dose estrogen products of high effectiveness have been developed." [Ex. 6, Pasquale at 1:10-13.] None of these references elaborated on the definition of "high" because no further definition was necessary. And none of these references qualified "high" in reference to prior art.

Extrinsic evidence confirms the ability of practitioners in the art to characterize the contraceptive reliability or efficacy of oral contraceptives as "high." "[T]he best indicator of claim

meaning is its usage in context as understood by one of skill in the art at the time of invention." *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1315 (Fed. Cir. 2003). Warner Chilcott's retained expert from its generic litigation over Lo Loestrin FE has written that "[o]ver the past 30 years, oral contraceptives (OCs) have consistently been shown to be highly effective contraceptive preparations." [Ex. 22, P. Darney, *Safety and efficacy of a triphasic oral contraceptive containing desogestrel: results of three multicenter trials*, 48 Contraception 323, 324 (1993) (stating that "[c]ontraceptive efficacy was high" for studied drug).] Dr. Darney is not alone in being able to determine when the contraceptive reliability of an oral contraceptive is "high." [Ex. 23, I. Arnt, et al., *Low-dose combination oral contraceptives: a controlled clinical study of three different norgestrel-ethinyl estradiol ratios*, 28 Fertility & Sterility 549, 553 (1977) (discussing class of oral contraceptives as having "high efficacy and low side effects") (WC_DEL_00034559-66); Ex. 24, European Pat. App. 0 499 348 A1 at 7:40-47 (Jan. 22, 1992)(stating that object of invention was "high contraceptive certainty") (WC_DEL_00035035-44); Ex. 25, S. Killick, et al., *Ovarian follicular development in oral contraceptive cycles*, 48 Fertility & Sterility 409, 409 (1987) (noting "high level of efficacy" of "the combined oral contraceptive (OC) pill") (WC_DEL_00035724-30); Ex. 26, B. Van Dierendonck, et al., *A multicenter clinical trial in Nigeria with a low-dose oral contraceptive, Marvelon*, 9 Advances in Contraception 25, 26 (1993) (class of oral contraceptives demonstrated "high contraceptive reliability") (WC_DEL_00036999-7007); *see also* Shulman Decl. ¶¶ 14-15.]

Despite this evidence, Warner Chilcott urges the Court to construe the term "high" as meaning "highest." That is wrong. A person of ordinary skill in the art would not understand Bayer to be claiming the "highest contraceptive reliability ever." As discussed, intrinsic prior-art references Ehrlich and Pasquale discuss "high contraceptive reliability" or "high effectiveness." [Ex. 2, Ehrlich at 3:37-38; Ex. 6, Pasquale at 1:11-13.] The inventors did not claim to have achieved "high

contraceptive reliability" for the "first time" when the intrinsic evidence taught that other regimens had already achieved it.

Importing the Pearl Index into the claim language is also improper. Although the Pearl Index is one way to assess contraceptive reliability, it is not the only way. The term "Pearl Index" does not appear in the claims, specification, or intrinsic evidence. There is no way, for example, for the public to reasonably compare the Pearl Index of the '940 patented regimen with the Pearl Index of the Ehrlich regimen because neither patent discusses its respective Pearl Index.

In fact, even if the indices were set forth in the prior art, a person of ordinary skill in the art would consider the Pearl Index to be a poor basis for comparison. Practitioners have long recognized the difficulties in comparing contraceptive efficacy using Pearl Indices. [Ex. 17, R. Hatcher, et al., *Contraceptive Technology* 121 (16th ed. 1994) (Pearl Index is "misleading when one wishes to compare failure rates obtained from studies with different average amounts of exposure.").] In fact, when not testifying here, Warner Chilcott's proffered expert cautions against the use of Pearl Indices for such a comparison, notwithstanding his opinions in this case:

> The problem with the PI is that failure rate for most contraceptives declines with continued use. Therefore, failure rates based on different study durations are not comparable. Additionally, the PI does not take into account the demographics of the study population, which can greatly affect the failure rate of a contraceptive method. . . . Given these [and other] issues with the PI, efficacy comparisons between studies become difficult.

[Ex. 27, J. Bitzer & J.A. Simon, *Current issues and available options in combined hormonal contraception*, 84 Contraception 342, 347 (2011) (internal citations omitted).] Instead, the proper assessment of a contraceptive is by comparing the results to when a woman is not using the contraceptive. [D.I. 61, Bayer Br. at 13-14.]

b. Low Incidence Of Follicular Development

The parties' dispute here is once again narrow. The parties do not ask the Court to construe the language "incidence of follicular development." Both proposed constructions employ the term.[4] Instead, the dispute concerns the word "low." Warner Chilcott again defines the term "low" to mean "lowest." Specifically, Warner Chilcott urges a construction that would require an incidence of follicular development that is lower than all of the prior art cited in Bayer's patent. Again, this construction is an invitation to error.

A person of ordinary skill in the art assesses the effect on follicular development from an oral contraceptive by comparing the amount of follicular growth during treatment with an oral contraceptive to follicular growth during the normal menstrual cycle. The patent's specification describes one such study in which follicular development was assessed. [Ex. 1, '940 Pat. at 2:61-67.] And the patent itself describes the degree of follicular development with traditional 21-7 regimens in terms of the "normal menstrual cycle." [Ex. 1, '940 Pat. at 4:19-28.] Other extrinsic evidence confirms this is the proper comparison. [Ex. 28, G. Shaw, et al., *Assessment of ovarian activity in a gestodene containing triphasic oral contraceptive*, 18 Brit. J. Family Planning 76, 77 (1992) (comparing hormone levels for purposes of assessing follicular / ovarian activity) (WC_DEL_00036408-11); Ex. 29, A.T. Teichmann, et al., *The influence of the dose of ethinylestradiol in oral contraceptives on follicle growth*, 9 Gynecol. Endocrinol. 299, 302 (1995) (comparing incidence of "follicle-like structures" to incidence during control cycle) (WC_DEL_00036706-12); *see also* Shulman Decl. ¶ 16.] The practice of comparing a contraceptive's performance to a regular menstrual cycle is common in the industry. As the head of clinical trials for Warner Chilcott for Lo Loestrin FE has testified elsewhere:

> Q The third entry was a requirement for regular menstrual cycles. What was the purpose of that as an inclusion criteria?

[4] Bayer of course disputes Warner Chilcott's claim that the term is indefinite. And the use of the term in the art demonstrates that the scope of this term is known to a reasonable certainty. *See Nautilus Inc. v. Biosig Instruments*, 134 S. Ct. 2120, __ U.S. __ (2014).

> A. If you are going to evaluate the effect on a menstrual cycle of any hormonal regimen you are testing for contraception, you have to start from a known, which in the case of oral contraceptive development and for this Femhrt product for perimenopausal women, regular cycles.

[Ex. 21, Ellman Dep. 65:21-66:8, Feb. 8, 2013 (WC_DEL_00076510-11).]

In addition, persons of skill in the art are able to characterize the "incidence of follicular development." During the follicular phase of the menstrual cycle, several follicle-like structures develop until a dominant follicle emerges which in turn creates an egg (oocyte) that is released when the follicle ruptures and ovulation occurs. [Ex. 17, R. Hatcher, et al., *Contraceptive Technology* 43-44.] A person of skill in the art is able to assess and characterize this development when evaluating contraceptives, including whether the development is "low." [Ex. 30, C. Fitzgerald, et al., *A comparison of the effects of two monophasic low dose oral contraceptives on the inhibition of ovulation*, 10 Advances in Contraception 5, 9, 11 (1994) (WC_DEL_00035422-36); Ex. 31, P. Lahteenmaki, et al., *Extension of the pill-free period by three days in oral contraceptive users* (Abstract), 11 Advances in Contraception 37-38 (1995) ("The follicular growth up to preovulatory size is ***common*** in OC users if the PF period is extended to 10 days.") (emphasis added) (WC_DEL_00035861-64); Ex. 32, P. Darney, et al., *Practice Guidelines for OC Selection*, 4 Dialogues in Contraception 1, 15 (1996) ("the follicular development ***rate*** of the multiphasic OC [in a previous study] was ***intermediate*** between the lower-dose and higher-dose monophasic OCs") (emphasis added) (WC_DEL_00036016-30).]

c. "Satisfactory Cycle Control" And "Reliable Avoidance of Intracyclic Menstrual Bleeding"

The parties dispute the constructions for both "cycle control" and "intracyclic menstrual bleeding." Warner Chilcott asks the Court to define both claim terms as "intracyclic menstrual bleeding (i.e., any bleeding occurring outside the hormone-free interval)." [D.I. 62, WC Br. at 13.] Those constructions are erroneous.

(1) Cycle Control

The specification does not limit "cycle control" to "intracyclic menstrual bleeding." [Ex. 1, '940 Pat. at 1:51-58, 6:32-37.] Neither does the intrinsic evidence. [Ex. 10, U.S. Pat. No. 5,633,242 at 3:30-35 ("Oettel") (regimen "combines high contraceptive safety with perfect cycle control while positively preventing intermenstrual bleeding and side effects.").] And neither does extrinsic evidence. [Ex. 24, EP 0499 348 A1 at 3:39-4:44 ("cycle control (regular withdrawal bleeding, least possible break-through bleeding)").]

"Cycle control" refers to such factors set forth in the specification as whether a woman is experiencing unwanted bleeding or spotting or whether a woman has a withdrawal bleed that mimics a healthy woman's cycle. [Ex. 1, '940 Pat. at 1:51-58, 6:33-38; Ex. 2, Ehrlich at 2:6-24, 3:36-39, 5:68-6:4.] The intrinsic evidence uses the term without elaboration but discusses the same types of events as consisting of cycle control. [*See, e.g.*, Ex. 2, Ehrlich at 1:48-51.] Extrinsic evidence confirms these aspects of cycle control and that persons of skill evaluate a contraceptive based on cycle control with known and acceptable methods for doing so. [*See, e.g.*, Ex. 33, P.G.T. Bye & M. Elstein, *Clinical assessment of a low-oestrogen combined oral contraceptive*, 2 Brit. Med. J. 389, 389 (1973) (discussing "satisfactory cycle control"); *see also* Shulman Decl. ¶¶ 17-22.]

A person of ordinary skill in the art also has no difficulty determining when cycle control is satisfactory or acceptable. To assess cycle control, persons of ordinary skill in the art evaluate the bleeding profile of a woman taking a contraceptive and determine whether it is acceptable to the women studied. [Ex. 19, D. Serfaty, *The 20 microgram ethinyl estradiol plus 150 microgram desogestrel pill multicenter study on 235 women for 6 months*, 18 Contraception 1, 6 (1990).] The assessment of cycle control is made based on a comparison to the normal menstrual cycle, as is demonstrated by studies evaluating cycle control and as confirmed by Warner Chilcott's expert in his deposition in litigation over Lo Loestrin FE. [Ex. 19, Serfaty at 3-5; Ex. 34 G. Benagiano & F.M. Primiero, *Multicenter clinical trial of an oral contraceptive with desogestrel plus 20 μg of ethinylestradiol in Italy*, *in* Mercilon: A New Era In

Low-Dose Oral Contraception 57-59 (1990) (comparing treatment cycles to "basal" or control cycles) (WC_DEL_0034629-39).]

Warner Chilcott's claim-construction expert says that persons of skill in the art are unable to understand when cycle control is "satisfactory." But his prior statements belie that opinion. Elsewhere, Dr. Simon has discussed the problems with estrogens that provide "unacceptable cycle control" based on studies that predate the '940 patent and has stated that "one of the goals of combined hormonal contraception is to provide the lowest estrogen exposure while maintaining ***good cycle control***." [Ex. 27, J. Bitzer & J.A. Simon, *Current issues and available options in combined hormonal contraception*, 84 Contraception 342, 343, 347, 352 (2011) (emphasis added) ("Previous attempts to include E2 as the estrogenic component of COCs were unsuccessful because of irregular bleeding and unacceptable cycle control.").]

In addition, Warner Chilcott's expert in litigation over its own patent covering Lo Loestrin FE said that "clinicians are less likely to prescribe . . . an oral contraceptive if it is associated with an unacceptable level of unscheduled bleeding" and she said previously had concerns with low-dose estrogen pills having "unacceptable cycle control." [Ex. 35, Expert Report of Risa Kagan, M.D. at 6, 11 (opining based on her "three decades" of practice) (WC_DEL_00074397, 74402, 74407); Ex. 36, Kagan Dep. 32:3-12, July 22, 2013 (providing definition of "poor cycle control") (WC_DEL_00076621).] Another of Warner Chilcott's experts from the same case made the same assessment at the time of the invention. [Ex. 22, P. Darney, *Safety and efficacy of a triphasic oral contraceptive containing desogestrel: Results of three multicenter trials*, 48 Contraception 323, 335 (1993) ("With triphasic DSG/EE, high contraceptive efficacy is combined with excellent cycle control.").] And with respect to the "withdrawal bleed" aspect of cycle control, the Warner Chilcott scientist who ran the clinical trial for Lo Loestrin FE said one aspect assessed for the drug was whether women could "have a withdrawal bleed predictably at the end of each cycle, that would meet the expectations of

physicians and women and be more acceptable to the user." [Ex. 21, Ellman Dep. at 208:11-23, Feb. 8, 2013 (WC_DEL_00076546).] Only here has Warner Chilcott or its experts said that people of skill in the art lack the ability to assess whether cycle control or its components are satisfactory.

(2) Intracyclic Menstrual Bleeding

Neither the patent nor the specification equates "intracyclic menstrual bleeding" with bleeding that occurs when no hormone is administered. To the contrary, the specification states that the administration of two placebo pills followed by unopposed estrogen pills "ensures withdrawal bleeding." [Ex. 1, '940 Pat. at 4:28-35.] The specification does not say that the withdrawal bleeding becomes "intracyclic menstrual bleeding" if it carries over into the days the woman is taking a hormone (unopposed estrogen). Intrinsic evidence also discusses bleeding occurring during days that a woman is taking a hormonal pill as withdrawal bleeding – not intracyclic bleeding. [Ex. 15, Lachnit at 4:38-45.]

In addition, clinical methods exist for assessing the amount of intracyclic menstrual bleeding – that is, unscheduled bleeding that occurs outside of the "withdrawal bleed." And a person of ordinary skill in the art can assess the reliability of avoiding intracyclic menstrual bleeding. [Ex. 34, G. Benagiano & F.M. Primiero, *Multicenter clinical trial of an oral contraceptive with desogestrel plus 20 μg ethinylestradiol in Italy*, *in* Mercilon: A New Era in Low-Dose Oral Contraception 57 (1990) ("The new preparation allowed a very satisfactory cycle control, with a ***low incidence of irregular bleeding***.") (emphasis added); Ex. 26, B. Van Dierendonck, et al., *A multicenter clinical trial in Nigeria with a low-dose oral contraceptive, Marvelon*, 9 Advances in Contraception 25, 30 (1993) ("Breakthrough bleeding, spotting and anemia ***remained incidental*** and the frequency declined over the period of observation.") (emphasis added); *see also* Shulman Decl. ¶ 23.] In fact, Warner Chilcott's expert from its Lo Loestrin FE litigation has elsewhere discussed studies comparing oral contraceptives that

"both had an equivalently low incidence of [breakthrough bleeding]." [Ex. 32, P. Darney, et al., *Practice Guidelines for OC Selection*, 4 Dialogues in Contraception 1, 7 (1996).]

d. Reliable Avoidance Of Undesirable Side Effects

The two basic disputes between the parties regarding this term are whether a person of ordinary skill in the art can assess the "reliable avoidance of undesirable side effects" and whether that assessment is made in comparison to a normal menstrual cycle. Warner Chilcott again repeats its arguments that "reliable" is a vague term and an assessment of "side effects" does not entail a comparison to healthy women who are not taking oral contraception. Both are wrong.

Warner Chilcott's dismisses Bayer's proposed construction as "mak[ing] no sense" because side effects do not exist when a woman does not take an oral contraceptive. That argument is a strawman. A person of ordinary skill in the art would not say that she was comparing the side effects from an oral contraceptive to the "side effects" of "not using a drug or therapy," and that is not what Bayer's construction entails. Whether an oral contraceptive produces an undesirable side effect depends on what happens when a healthy woman does not take that oral contraceptive. [Ex. 26, B. Van Dierendonck, et al., *A multicenter clinical trial in Nigeria with a low-dose oral contraceptive, Marvelon*, 9 Advances in Contraception 25, 28-29 (1993) ("There was no statistically significant difference in pretreatment values and 6 month values for breast tenderness, nervousness and depression. There is a small but significant decline in headache and also an increase in nausea after 6 months, compared to pretreatment values."); *see also* Shulman Decl. ¶¶ 24-25.] It is called a control. And it is a standard scientific method for assessing causation, as Warner Chilcott's clinical-trial leader explained above. [*Infra* at 6.]

Persons of ordinary skill in the art have methods for assessing the occurrence of side effects from an oral contraceptive. And persons of ordinary skill are likewise able to assess whether a person reliably avoids undesirable side effects while taking the oral contraceptive as compared to a

healthy woman who is not taking the oral contraceptive. [Ex. 19, D. Serfaty, *The 20 microgram ethinyl estradiol plus 150 microgram desogestrel pill multicenter study on 235 women for 6 months*, 18 Contraception 1, 6 (1990) (comparing incidence of side effects before and after treatment with oral contraceptive).]

II. Warner Chilcott's Construction of "Effective Estrogen Content" In Claim 1 Would Gut Several Dependent Claims

Warner Chilcott asks the Court to set a floor by construing an "effective estrogen content" to be the lowest amount of estrogen discussed in the specification or claims. That construction is unsupported and inconsistent with the claims and specification.

First, Warner Chilcott speculates that the inventors would have described regimens with less than 15 μg of ethinyl estradiol "if they believed that such an estrogen content would be 'effective.'" (D.I. 62, WC Br. at 17.) Warner Chilcott cites nothing in support of this proposition. Even if Warner Chilcott had evidence of what the inventors intended, accepting their construction on these grounds would be legal error. "[T]he subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim." *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346 (Fed. Cir. 2008) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 985 (Fed. Cir. 1995)). Of even less probative weight is speculation without citation as to what the inventors would have "preferred" or "believed." Further, the failure to include a specific embodiment in the specification is irrelevant to claim construction. "The law does not require the impossible. Hence, it does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). The claim language dictates the scope of the claim, and the claim language does not set the floor Warner Chilcott asks the Court to impose.

Second, Warner Chilcott also says that the specification teaches away from the use of less than 20 μg of ethinylestradiol. It does not. The "risk of pregnancy" from a 20 μg oral contraceptive described in the patent was based on prior-art regimens that only administered estrogen for 21 days

– not the 26 days of estrogen in either the combined pill or the unopposed estrogen pill. In fact, the risk from using low doses of estrogen in the traditional 21-7 regimen was one of the problems solved by the claimed invention. The patent did not teach away from using low doses of estrogen. And no one would understand the inventors to be criticizing the use of less than 20 μg of ethinyl estradiol in the claimed regimen when the claims describe using less than 20 μg of ethinyl estradiol.

Third, Warner Chilcott's proposed construction commits the cardinal sin of claim construction: ignoring the claim language and importing limitations from the specification. "The general rule, of course, is that claims of a patent are not limited to a preferred embodiment, unless by their own language." *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003). But the only support for the "effective estrogen content" construction that Warner Chilcott offers is one of the embodiments described in the specification. [D.I. 62, WC Br. at 17-18.] The patent offers more than one embodiment, including those that do not recite any lower limit on the amount of ethinyl estradiol. [Ex. 1, '940 Pat. at 4:36-57.] And the inventors did not disavow any embodiments. *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1354 (Fed. Cir. 2003) (reversing construction limiting claim to embodiment because "not a case in which the specification disavows any embodiment other than" the one set forth in the specification).

Finally, by importing an embodiment into claim 1, Warner Chilcott's estrogen-floor construction renders four dependent claims meaningless. The patent teaches the person of skill in the art to use "an estrogen content that is as low as possible." [Ex. 1, '940 Pat. at 3:40-49.] And at the time of the invention, 50 mcg of ethinyl estradiol was considered a "higher dose estrogen." [Ex. 17, R. Hatcher, et al., *Contraceptive Technology* 255.] Absent contradicting the patent's teaching and using what practitioners considered to be a "higher dose" of estrogen at the time, Warner Chilcott's proposed construction would make four claims redundant by importing the estrogen-dose limitations from those dependent claims into claim 1.

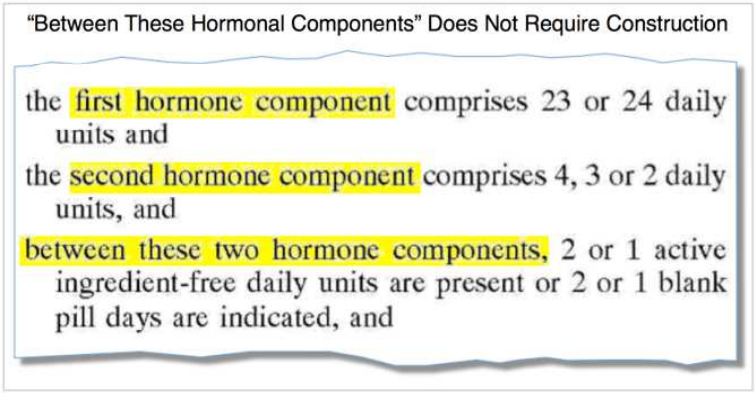
Claims			
1			"effective estrogen content"
--	3		~~15 to 25 mcg of ethinyl estradiol~~ (combined pills)
--	4		~~2 to 40 mcg of ethinyl estradiol~~ (estrogen-only pills)
	--	5	~~10 to 15 mcg of ethinyl estradiol~~ (estrogen-only pills)
--	9		~~15 to 25 mcg of ethinyl estradiol and 2 to 40 mcg of ethinyl estradiol~~

[Ex. 1, '940 Pat. at 7:35.] But "[i]t is settled law that when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim in determining either validity or infringement." *SRI Int'l*, 775 F.2d at 1122; *Lucas Aerospace, Ltd. v. Unison Indus., L.P.*, 890 F. Supp. 329, 338 (D. Del. 1995) ("The 'presumed . . . difference in meaning and scope when different words or phrases are used in separate claims' . . . disappears" if limitations of dependent claims are read into independent claim) (citation omitted). Warner Chilcott's construction violates this "settled law" whereas Bayer's construction preserves the differences between claim 1 and its dependent claims.[5]

III. "Between These Two Hormone Components" Does Not Require Construction Or Expert Testimony

The term "between these two hormone components" does not require construction because its meaning is clear from the claims. No jury will be confused by the use of a common preposition ("between") relating "two hormone components" when the claim itself discusses two "hormone component[s]."

[5] Warner Chilcott also argues that a person of skill in the art would understand the 24 combined pills to have more estrogen than the 2 unopposed-estrogen pills. It is unclear what relevance this has to claim construction. But the premise that prior-art regimens do not have the same amount of estrogen in combined and unopposed-estrogen pills is false. [Ex. 2, Ehrlich at 6:15-29 (claiming regimen with 10 unopposed-estrogen pills and 18 combined pills, all with same amount of ethinylestradiol; *see also* Shulman Decl. ¶ 27.] And the patent itself claims overlapping ranges for both the combined and the unopposed-estrogen pills. [Ex. 1, '940 Pat. at 8:38-59.]



Warner Chilcott's proposed claim-construction expert devotes three paragraphs to opining that the word "between" means what everyone thinks it means and scouring the specification to find the "hormone components" even though claim 1 itself identifies two "hormone components." [D.I. 63, Simon Decl. ¶¶ 32-34.] And Warner Chilcott and its expert rewrite the claim language by converting pills consisting "essentially of an estrogen preparation" into pills with "estrogen only." [*Id.* at ¶ 32; D.I. 62, WC Br. at 19-20.] There is no need to construe this term (let alone consult a reproductive endocrinologist) because anyone would understand its meaning. But if the Court does construe the claim, Bayer's construction is more straightforward based on the claim language.

OF COUNSEL:
Adam K. Mortara
Matthew R. Ford
Andrew C. MacNally
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 W. Hubbard Street, Suite 300
Chicago, IL 60654
(312) 494-4400

Sundeep K. (Rob) Addy
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
1899 Wynkoop Street, 8th Floor
Denver, CO 80202
(303) 592-3100

BAYARD, P.A.

/s/ Richard D. Kirk
Richard D. Kirk (rk922)
Stephen B. Brauerman (sb4952)
Vanessa R. Tiradentes (vt5398)
Sara E. Bussiere (sb5725)
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899
Phone: (302) 655-5000
rkirk@bayardlaw.com
sbrauerman@bayardlaw.com
vtiradentes@bayardlaw.com
sbussiere@bayardlaw.com

Attorneys for Plaintiffs Bayer Intellectual Property GmbH and Bayer Pharma AG

June 13, 2014